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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL A. MASINI

Appeal 2008-4427
Application 10/706,570
Technology Center 3700

Decided: January 6, 2009

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to bandages and packaging for bandages. We have jurisdiction under 35 U.S.C. § 6(b). We reverse and enter a new ground of rejection.

Statement of the Case

Background

“The removal of bandages and other wound dressings is an area where further safety measures are warranted. There are no composite wound dressings which integrate adhesive and absorbent layers in combination with a fluid impermeable cover” (Spec. 2:2-6). The Specification notes that “not only are the edges of the absorbent pad taped to the patient, but excessive tape is often used to cover the entire pad outer surface to ensure a fluid-tight seal” (Spec. 2:8-11). According to the Specification, the “used bandages are discarded by placing them into specially marked bags . . . This practice may expose associated personnel to dangerous pathogens since until such dressings are placed in their specially marked disposal containers, the surfaces once applied to the patient are outwardly unprotected” (Spec. 2:14-20).

The Claims

Claims 11, 12, 15-17, 20-23, 25-28, 43, and 44 are on appeal.¹ We will focus on claims 1, 16, and 25 which are representative and read as follows:

11. Packaging for a bandage having a patient-contacting surface with a peripheral edge, the patient-contacting surface, including an absorbent layer completely surrounded by an adhesive that extends to the peripheral edge in all directions, comprising:

first and second removable sheets, both extending beyond the peripheral edge of the bandage and peripherally

¹ Claims 13, 14, 18, 19, and 29-42 were withdrawn from consideration (App. Br. 1).

joined so that the bandage is contained between the removable sheets until use; and

wherein one of sheets is in direct contact with the entire adhesive on the patient-contacting surface until that sheet is removed.

16. A bandage construction, consisting of a bandage portion having a patient- contacting front surface with an adhesive, a back surface and a peripheral edge; and

a packaging portion including first and second removable sheets, both extending beyond the peripheral edge of the bandage, and wherein the first and second removable sheets are peripherally joined so that the bandage is contained between the removable sheets until use.

25. The bandage construction [of claim 16 wherein the bandage portion comprises: a flexible backing layer; and an absorbent layer bonded to the flexible backing layer and]

wherein the flexible backing layer is fluid-impermeable.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Bush	US 2,897,961	Aug. 4, 1959
Etheredge	US 5,333,753	Aug. 2, 1994
Newman	US 5,586,971	Dec. 24, 1996

The issues

A. The Examiner rejected claims 11, 12, 15-17, 20-23, and 26-28 under 35 U.S.C. § 102(b) as being anticipated by Etheredge (Ans. 4-6).

B. The Examiner rejected claim 25 under 35 U.S.C. § 103(a) as being obvious over Etheredge and Bush (Ans. 7).

C. The Examiner rejected claims 43 and 44 under 35 U.S.C. § 103(a) as being obvious over Etheredge and Newman (Ans. 7-8).

A. 35 U.S.C. § 102(b) as being anticipated by Etheredge

The Examiner found that the “Etheredge discloses a packaging for a bandage (32) having a patient contacting surface with a peripheral edge (outer edges of device in see fig 3), the patient-contacting [sic] surface (36)” (Ans. 4). The Examiner further found that the Etheredge packaging included “an absorbent layer (34) completely surrounded by an adhesive that extends to the peripheral edge in all directions (column 2 lines 46-51) comprising first and second removable sheets (12,22), both extending beyond the peripheral edge of the bandage and peripherally joined (column 3 lines 23-28)” (Ans. 4). The Examiner also found “that the bandage is contained between the removable sheets until use (see fig 2) and one of sheets is in direct contact with the entire adhesive (42) on the patient-contacting surface until that sheet is removed” (Ans. 4).

Appellant contends that

the Examiner's last statement, that "one of the sheets is in direct contact with the entire adhesive (42) on the patient-contacting surface until that sheet is removed" is incorrect. While item 42 is an adhesive, it is a small strip that keeps sheet 12 attached to sheet 38. This adhesive is *not* adhesive (42) on the patient-contacting surface of the bandage. Indeed, sheet 38 *prevents* the sheet 12 from making contact to any of the adhesive (42) on the patient-contacting surface of the bandage.

(App. Br. 4.)

Appellant also contends that “independent claims 16 and 28 are *consisting of* claims The packaging system of Etheredge includes many

other elements, including the sheets 38, 40 and the adhesive strip 42.
Accordingly prima facie anticipation has not been established” (App. Br. 5).

In view of these conflicting positions, we frame the anticipation issues before us as follows:

(1) Did the Examiner err in finding that Etheredge teaches one of the sheets is in direct contact with the entire adhesive on the patient contacting surface until that sheet is removed?

(2) Did the Examiner err in finding that Etheredge anticipates claim 16, since claim 16 uses “consisting of” in the preamble and Etheredge incorporates additional elements not found in claim 16?

Findings of Fact (FF)

1. Etheredge teaches a bandage as shown in Fig. 2 reproduced below:

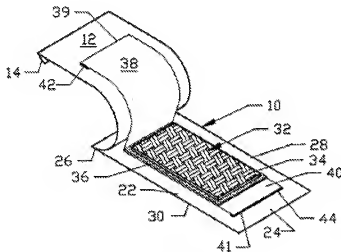


Fig. 2

“FIG. 2 is a perspective view of the package and delivery system of FIG. 1 with the cover sheet peeled back to reveal the bandage” (Etheredge, col. 2, ll. 18-20).

2. Etheredge teaches a bandage as shown in Fig. 3 reproduced below:

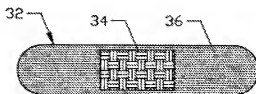


Fig. 3

“FIG. 3 is a bottom plan view of the finger bandage as removed from its package” (Etheredge, col. 2, ll. 21-22).

3. Etheredge teaches “a packaging and dispensing system wherein the bandage has the free ends on either side of the absorbent pad folded inwardly to make a significantly smaller package” (Etheredge, col. 1, ll. 59-62).

4. Etheredge teaches that “bandage **32** . . . is a conventional finger bandage . . . having an absorbent pad **34** substantially centrally positioned on the adhesive surface **3** of the bandage, leaving free adhesive on either side of the pad for securing the bandage to the skin” (Etheredge, col. 2, ll. 56-51).

5. Etheredge teaches that “[o]uter sheets **12, 22** are conventional packaging material and may be made of paper or plastic. They may be sealed around their common periphery, as heretofore described by per se known pressure-sensitive adhesives or by heat sealing” (Etheredge, col. 3, ll. 22-26).

6. Etheredge teaches “release sheets **38,40** covering [sic, covering] adhesive **36** of the bandage” (Etheredge, col. 3, ll. 20-21).

7. The Examiner finds that “one of sheets is in direct contact with the entire adhesive (42) on the patient-contacting surface until that sheet is removed” (Ans. 4).

8. The Examiner finds that “[s]ince the layer (38) is in direct contact with removable sheet (12) by adhesive (42), the sheets essentially define one layer and they must be in contact with the adhesive when pressed down on the wound or patient contacting surface” (Ans. 8-9).

Principles of Law

“A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference.” *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed.Cir.1994); *see Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed.Cir.2001) (“Invalidity on the ground of ‘anticipation’ requires lack of novelty of the invention as claimed that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim.”).

Claim terms are interpreted using the broadest reasonable interpretation in light of the Specification. *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (“[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.”). *Also see In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997). (“Absent an express definition in their specification, the fact that appellants can point to definitions or usages that conform to their interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation.”)

Analysis

Claim 11

Etheredge teaches packaging for a bandage with an absorbent layer completely surrounded by adhesive that extends to the peripheral edge including first and second removable sheets which are peripherally joined (FF 1-6). The Examiner finds, presumably using the broadest reasonable interpretation rule, that “[s]ince layer (38) is in direct contact with removable sheet (12) by adhesive (42), the sheets essentially define one layer” (Ans. 8). The Examiner is interpreting Etheredge to permit two layers, layer 38 and layer 12, to be combined in order to satisfy a claim requirement for a single sheet that is “in direct contact with the entire adhesive on the patient contacting surface” (Claim 11).

Appellant’s Specification clearly indicates that “two outer sheets 12 and 14 are used to entirely contain the bandage, and are accordingly the only materials that need to be discarded upon application” (Spec. 8:10-12). The Specification clearly indicates that the layer 14 on the adhesive side is a single sheet (*see* Spec. 8:10-12).

Even using the broadest reasonable interpretation rule, the rejection unreasonably interprets two layers, layer (38) and layer (12) as being one sheet. Two layers are not the single sheet of claim 11, which must satisfy two requirements. The first requirement for the sheet of claim 11 is to “extend beyond the peripheral edge of the bandage” and be peripherally joined to the other sheet (Claim 11). The second requirement for the single sheet of claim 11 is to be “in direct contact with the entire adhesive on the patient-contacting surface” (Claim 11). Neither layer (38) of Etheredge,

which contacts the absorbant pad and some of the adhesive but does not extend beyond the peripheral edge of the bandage, nor layer (12) which extends beyond the peripheral edge of the bandage but does not contact the entire adhesive, satisfy the requirements for the single sheet of claim 11.

Claim 16

The Examiner contends that the “only elements of bandage that are affected by the ‘consisting of’ closed-ended claim language are the macro elements” (Ans. 9). The Examiner argues that the “‘consisting of’ language does not prevent further limiting these macro elements but only the addition of other macro elements” (Ans. 9).

The Examiner’s understanding of “consisting of” is flatly inconsistent with Federal Circuit case law. “It is equally well understood in patent usage that ‘consisting of’ is closed-ended and conveys limitation and exclusion” *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1361 (Fed. Cir. 2007). *See Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed.Cir.2004) (“‘consisting of’ is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim ... [however] . . . it does not limit aspects unrelated to the invention.”)

The Examiner would change this rule to permit additional elements for “macro elements” when “consisting of” is used (Ans. 9). The Examiner cites no basis for this interpretation of the law.

The Examiner suggests that “including” in claim 16 is inconsistent with “consisting of”. In claim 16, the precise phrase with “including” is “a packaging portion including first and second removable sheets” (Claim 16). There is no necessary inconsistency. Reading this as an ordinary English

phrase, “including” is simply used to define the two elements of the packaging portion. The word “including” does not require that additional elements are present. In view of the term “consisting of” in the claim preamble, we interpret “including” not to open the claim to additional elements. We also draw the same conclusion for the term “having” with respect to the “bandage portion”, i.e., that it does not open the claim to additional elements.

The Examiner relies on *Mannesmann* to suggest that the presence of the word “including” in claim 16 renders the claim “open”. The Examiner misreads the holding in *Mannesmann*. In *Mannesmann*, the court found that the “district court correctly observed that the phrase ‘consisting of’ appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a).” *Mannesmann Demag Corp. v. Engineered Metal Products Co., Inc.*, 793 F.2d 1279, 1282 (Fed. Cir. 1986). This is in contrast to instant claim 16, where the “consisting of” is in the preamble, not in one clause of the claim. Consequently, *Mannesmann* is consistent with Appellant’s argument that “‘consisting of’ excludes any element step or ingredient not specified in the claim . . . The packaging system of Etheredge includes many other elements, including the sheets 38, 40, and the adhesive strip 42” (App. Br. 5).

Conclusions of Law

(1) The Examiner erred in finding that Etheredge teaches “one of the sheets is in direct contact with the entire adhesive on the patient contacting surface until that sheet is removed”.

(2) The Examiner erred in finding that Etheredge anticipates claim 16, since claim 16 uses “consisting of” in the preamble and Etheredge incorporates additional elements not found in claim 16.

B. 35 U.S.C. § 103(a) as obvious over Etheredge and Bush

The Examiner rejected claim 25 under 35 U.S.C. § 103(a) as being obvious over Etheredge and Bush (Ans. 7).

The Examiner states that “Etheredge substantially disclose[s] the invention” (Ans. 7). The Examiner relies upon Bush solely for a fluid-impermeable backing layer (*see* Ans. 7).

Appellant contends that “[w]ith regard to the rejection of claims 25 . . . combining the primary reference of Etheredge with secondary references adds even more elements to the basic combination, thereby further distinguishing over Appellant’s consisting of claims” (App. Br. 5).

In view of these conflicting positions, we frame the obviousness issue before us as follows:

Did the Examiner err in finding that the combination of Bush and Etheredge rendered obvious claim 25, which incorporates the closed “consisting of” language of claim 16?

Findings of Fact

9. Bush teaches “individual adhesive bandages of the type having a flexible backing coated with a pressure-sensitive adhesive composition” (Bush, col. 1, ll. 15-17).

10. Bush specifically teaches a bandage as shown in Fig 3, reproduced below:



“Fig. 3 is a longitudinal section of the adhesive bandage package unit”
(Bush, col. 2, l. 32).

11. Bush teaches “the adhesive bandaged package unit comprises an adhesive bandage which includes adhesive tape in strip . . . and the wrapper for said adhesive tape includes a sheet of flexible material adhesively attached to the adhesive side of the adhesive tape to serve not only as a wrapper sheet but also as a protective facing therefor” (Bush, col. 1, ll. 63-69).

12. Bush teaches that “a finger tab by which the wrapper sheet may be conveniently grasped and easily stripped away from the adhesive tape” (Bush, col. 2, ll. 1-2).

13. Bush teaches that “[t]o allow for the handling of the adhesive bandage 10 after being almost withdrawn from the wrapper 11, without the fingers coming into contact with the adhesive side of the bandage, there is provided an insert 30” (Bush, col. 4, ll. 5-9).

14. Bush teaches that “such bandages are sterile and are packaged individually in such a manner that sterility is maintained until the individual package is opened” (Bush, col. 1, ll. 28-30).

Principles of Law

In *KSR*, the Supreme Court rejected the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, stating that

The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the

combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740 (2007).

However, in the case where a reference specifically criticizes an alternative, the reference teaches away from that alternative. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.”).

Analysis

For purposes of claim interpretation, we will treat claim 25 as closed, because the preamble of claim 16, from which claim 25 ultimately depends, uses “consisting of”.

While Etheredge does not satisfy the requirements of claims 11 or 25 for the reasons discussed above, the secondary reference, Bush, discloses a bandage which is much closer to the bandage of claims 11, 16 and 25. Bush teaches a bandage which has first and second removable sheets with a bandage with an absorbent layer between them (FF 9-11). Bush differs from the claims by including a finger tab (or insert 30) (FF 12-13).

The combination of Etheredge and Bush does not render claim 25 (or independent claims 11 or 16, and claim 22) obvious because Etheredge includes the extra layer as discussed above and Bush requires the finger tab

to be present to protect the bandage's sterility (FF 13). Neither Bush nor Etheredge teach forming a bandage without additional elements and neither Bush nor Etheredge teach forming a bandage "wherein one of the sheets is in direct contact with the entire adhesive on the patient-contacting surface" (Claim 11).

To the extent that an ordinary practitioner would recognize that the tab or insert of Bush need not be included, Bush teaches away from forming the bandage without the tab (FF 13-14). Bush teaches that the tab permits application of the bandage in a sterile manner (FF 13). Therefore, an ordinary practitioner would have been discouraged from removing the tab, since removal of the tab, according to Bush, would have reduced sterility, an important element in bandages (FF 14).

Conclusions of Law

The Examiner erred in finding that the combination of Bush and Etheredge rendered obvious claim 25, which incorporates the closed "consisting of" language of claim 16.

C. 35 U.S.C. § 103(a) as obvious over Etheredge and Newman

The Examiner rejected claims 43 and 44 under 35 U.S.C. § 103(a) as being obvious over Etheredge and Newman (Ans. 7-8).

Claims 43 and 44 depend from claim 16, which has a closed "consisting of" preamble. Claims 43 and 44 further describe the bandage portion. The Examiner has not provided a reason as to why persons of ordinary skill in the art would have formulated bandages without the additional elements shown in Etheredge. While no explicit suggestion in the prior art is necessary to establish prima facie obviousness, the Examiner still

has a burden of explaining why a person of ordinary skill in the art would have been prompted to modify the prior art to make the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

Accordingly, we reverse the rejection of claims 43 and 44.

New ground of rejection

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection.

Claims 22, 23, 25, and 26 are rejected under 35 U.S.C. § 112, second paragraph, as vague and indefinite.

Claim 22 depends from claim 16, whose preamble uses “consisting of”. Claim 22 is directed to the bandage construction of claim 16, “wherein the bandage portion comprises:” a backing layer and an absorbent layer.

While we interpreted claim 22 as closed for prior art purposes above, the claim has inherently conflicting clauses, since the preamble uses the closed “consisting of” language with “comprises” in the claim body. It is therefore indefinite if the claim phrase following “comprises” in claim 22 is open or closed, and what scope is encompassed by “bandage portion comprises”.

In our opinion, the direct conflict in claim 22 between open and closed language renders the claim “insolubly ambiguous”. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005) (citations omitted). (“Only claims ‘not amenable to construction’ or ‘insolubly ambiguous’ are indefinite”).

Additionally, however, the recent *Miyazaki* decision also supports finding this claim indefinite, since

The Federal Circuit has, however, noted that a different standard for indefiniteness may be appropriate during prosecution of patent claims. *See Exxon Research and Engineering Co. v. U.S.*, 265 F.3d 1371, 1384 (Fed. Cir. 2001) ("If this case were before an examiner, the examiner might well be justified in demanding that the applicant more clearly define UL, and thereby remove any degree of ambiguity. However, we are faced with an issued patent that enjoys a presumption of validity.") Accordingly, we adopt this lower threshold standard of ambiguity for indefiniteness for claims during prosecution in keeping with the USPTO's broadest reasonable interpretation standard for claim construction.

Ex Parte Kenichi Miyazaki, 2008 WL 5105055 (BPAI 2008).

SUMMARY

In summary, we reverse the rejection of claims 11, 12, 15-17, 20-23, and 26-28 under 35 U.S.C. § 102(b) as being anticipated by Etheredge. We also reverse the rejections of claims 25, 43, and 44 under 35 U.S.C. § 103(a).

We enter a new ground of rejection on claims 22, 23, 25, and 26.

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED; 37 C.F.R. § 41.50(b)

Ssc:

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